

AUG 10 2004

K040651

p1/2

510(k) Summary

HomMed Sentry IIIB-F Patient Monitor System

Consultant Contact: Tommie J. Morgan, Ph.D., President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008
713 880-5111 Voice or 713 880-3494 Fax

Company: HomMed, LLC
19275 West Capitol Dr., Suite 200
Brookfield, WI 53045
262 783-5440 Voice or 262 783-5441 Fax

Trade Name: HomMed Sentry IIIB-F Patient Monitor System

Common Name: Patient Vital Signs Monitor with Options

Classification Name: Cardiovascular and Respiratory Devices, Class II

Substantial Equivalence Claimed to:
HomMed Sentry III Patient Monitor System with Card Reader K014025

Device Description: The HomMed Sentry IIIB-F Patient Monitor System (Sentry IIIB-F) is a portable patient vital signs monitoring system. The system measures noninvasive blood pressure, pulse rate, oral temperature, oximetry, and weight. In addition, the system has optional glucometer, spirometer, electrocardiogram (ECG) and prothrombin time (PT/INR) measuring, and digital image acquisition capabilities. The Sentry IIIB-F acquires the patient vital signs data and displays it. The data can also be transmitted via the communication system through the Skytel or PageNet Pager Network to a central station for storage with retrospective display and analysis.

Indications for Use: The HomMed Sentry IIIB-F is intended for in home and/or healthcare facility applications under physician orders. The use of the system is to allow retrospective review of certain patient physiological functions. The HomMed Sentry IIIB-F can measure and display patient data including noninvasive blood pressure, pulse rate, oral temperature, oximetry, and weight. Additionally, the patient vital signs data can be communicated to a central review station via a pager network with a backup landline telephone modem for telephone communication with the central pager network if necessary.

Sentry IIIB-F provides a noninvasive blood pressure (NIBP) monitor for measurements of a patient's systolic, diastolic, and mean arterial (MAP) blood pressures; pulse oximeter, acquires a pulse rate using an oximeter; oral temperature via an electronic thermometer; weight from an electronic scale. All data collected from these functions as well as optional glucometry, spirometry, ECG devices, PT/INR monitor and acquired digital images are sent through an internal communication module.

The device will provide fast, reliable measurements on patients when using the appropriate blood pressure cuff. Sentry IIIB-F's pulse oximetry works with the

Sentry pulse oximetry probes provided by HomMed, providing SpO2 and pulse rate on all patients. The electronic thermometry requires use of the Welch Allyn oral thermometry probe and probe covers. It provides only oral temperature information.

Comparison with Predicate Devices:

This HomMed Sentry IIIB-F allows uncomplicated measurement and remote monitoring of patient vital signs including weight utilizing the existing technologies of the predicate device, HomMed Sentry III Patient Monitor System with Card Reader.

Determination of Substantial Equivalence:

The performance of each component of the HomMed Sentry IIIB-F has been confirmed to be equivalent to the predicate device HomMed Sentry III Patient Monitor System with Card Reader.

Compliance to Standards and Regulations:

The HomMed Model Sentry IIIB-F complies with the following national and international standards:

Safety	EN 60601-1	Medical Electrical Safety
	IEC 601-1-2	EMC Compliance
	ISO 10993-5,10-11	Biocompatibility

Performance Data:

The HomMed Sentry IIIB-F is utilized within the environments for which it and Sentry III with Card Reader are marketed. The Sentry IIIB-F performs consistent with guidelines and standards found in the FDA reviewer's guides for respiratory devices and electronic thermometers. EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed demonstrating compliance with applicable standards. The test results demonstrated that the Sentry IIIB-F is in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

The HomMed Sentry IIIB-F performance is consistent with the HomMed Sentry III with Card Reader performance. Testing done on the Sentry III IIIB-F assures compliance with applicable electrical, safety and healthcare standards. Thus it is the HomMed position that the HomMed Sentry IIIB-F performs as well as the legally marketed predicate device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding patient monitors.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2004

HomMed, LLC
c/o Tommie J. Morgan, Ph.D.
President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008

Re: K040651

Trade Name: HomMed Sentry IIIB-F Patient Monitor System
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: II (two)
Product Code: DXH
Dated: July 29, 2004
Received: July 30, 2004

Dear Dr. Morgan:

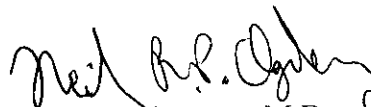
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D. *for*

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K040651

Device Name: HomMed Sentry IIIB-F Patient Monitor System

Indications for Use

The HomMed Sentry IIIB-F Patient Monitor System is designed to measure Patient Vital Signs in the home by patients or in clinical environments by health care providers. The HomMed Sentry IIIB-F Patient Monitor System is available with physicians' orders only.

The HomMed Sentry IIIB-F Patient Monitor System measures the following parameters: Non-Invasive Blood Pressures (Systolic, Diastolic and Mean Arterial Pressure), Functional Oxygen Saturation (%SpO₂), Peripheral Pulse Rate (PPR), Pulse Strength, Oral Temperature and Patient Weight via an external scale. The HomMed Sentry IIIB-F Patient Monitor System's optional, compatible devices extend those measurements to glucometer, spirometer, electrocardiogram (ECG) and prothrombin time (PT/INR) monitoring and digital image acquisition. The patient parameter data is collected and displayed by the HomMed Sentry IIIB-F Patient Monitor System. Data can be transmitted via the communication module to a central station where the patient data can be viewed and analyzed.

Prescription Use X
(21 CFR 807 Subpart D)

AND/OR

Over-the-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil A. P. [Signature]
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K040651

Page 1 of